

## **10.0 ACCESS TO DATA**

**10.1 ACCESS TO DATABASE.** Only OPTN contractor staff, or individuals engaged by or adjunct to contractor staff who are bound by contracts which prohibit competing interests and breaches of confidentiality, will be permitted to program UNet<sup>SM</sup> or have direct access to data within UNet<sup>SM</sup> or maintained in any other form. OPTN members requesting access to data regarding their own candidates and recipients will be provided access to that information when practicable as determined by the OPTN Project Director. Except as provided for in Policy 9.0 and this Policy 10.2 and Policy 10.3, neither individuals nor members will be given access to individual candidate-, recipient- or member-specific information other than that from their own organization, without prior written approval from those individuals or members identified. Candidate-, recipient- and institution-identified data will be made available to the Scientific Registry for Transplant Recipients (SRTR) Contractor.

**10.2 TRANSFER OF INFORMATION.** All requests for data should be made through the Data Request System. Routinely available data will comprise the following:

- Data provided in regularly updated Standard Reports;
- Data requested by OPTN members regarding their own institution and/or candidates and recipients;
- Data requested by the Department of Health and Human Services.

Requests involving twenty hours or more of programming time or any statistical analyses that are considered to be extensive may be subject to additional requirements (see Policy 10.3, Specific Projects).

Unless they are releasable according to Policy 9.0 or Policy 10.2, data will be provided with the deletion of all candidate-, recipient- and center-specific identifying information. Comprehensive datasets with center and candidate and recipient identifying information encrypted may be given out for research purposes with the approval of the Policy Oversight Committee (its chair plus representative committee members). Under some circumstances, center-specific data (standard analysis files) not otherwise releasable may be provided to bona fide researchers, subject to the approval of the Policy Oversight Committee using as guidance the Agreement for Release of Data, as approved by that Committee. In order to obtain these data, the submitting individual must meet the conditions for their release and sign an Agreement for Release of Data, which sets forth confidentiality and security stipulations for the data's release and use. Such data may be provided on a cost reimbursement basis. Use of such data will require written acknowledgment of the source of the data and the date it was provided (see Policy 10.4). As contractually required, the OPTN contractor may release records which are identifiable as to candidate, recipient, transplant center or OPO without a signed Agreement for Release of Data only pursuant to official requests for data from the Department of Health and Human Services in accordance with federal or state laws and regulations.

**10.3 SPECIFIC PROJECTS.** Any individual or group requesting data requiring twenty or more hours of programming time and/or any statistical analysis of a specific question by the OPTN contractor staff may be asked to submit a written concept paper to the Policy Oversight Committee. The Policy Oversight Committee (its chair plus representative committee members) will vote to approve or disapprove each request, and may also prioritize approved requests, based on scientific or clinical merit, importance to the OPTN, and the potential ability to address the question. The approval and priority status of each request will be provided to the submitting individual. Upon approval, the submitting individual will be notified of the OPTN contractor staff assigned to complete the request. The submitting individual must indicate to the assigned staff whether he/she wishes to be directly involved in the analysis and the project work group.

Data will be provided with the deletion of all candidate- and recipient-specific identifying information. Center-identifiers may be provided to bona fide researchers who meet the conditions specified in Agreement for Release of Data, which sets forth confidentiality and security stipulations for the data's release and use. Such data may be provided on a cost reimbursement basis. Use of such data will require written acknowledgment of the source of the data and the date it was provided (see Policy 10.4).

**10.4 PUBLIC USE, PRESENTATIONS AND PUBLICATIONS.** All scientific data provided and/or analyses performed by the OPTN contractor utilizing data collected for the OPTN must adhere to the following specific requirements regarding approval, content, confidentiality, and authorship:

**10.4.1 Public Use or Presentation of Specific Projects or Studies.** The scientific and analytical content of all abstracts or manuscripts developed from customized data requests, comprehensive encrypted datasets, or standard analysis files must be approved by the Policy Oversight Committee and any ad hoc work group appointed by that Committee prior to their public presentation or publication. If the analysis has not been provided prior to release by the investigator or institution, the OPTN contractor cannot assume responsibility for the correctness of the findings or interpretations. Failure to include the OPTN contractor in pre-release preparation may be an adverse consideration in subsequent applications by the investigator or institution for additional data. Any contractor staff who makes a significant intellectual contribution to a study abstract, presentation, or manuscript should be offered the opportunity to be included as an author. Contractor staff may not be listed as study authors without obtaining written permission from the appropriate staff. A copy of all published abstracts, manuscripts, or news releases should be submitted to staff and/or the Policy Oversight Committee for informational purposes as soon as practicable.

**10.4.2 Data Obtained Through the Data Request System.** Abstracts and manuscripts prepared using routinely available data obtained through the data request system do not require approval by the Policy Oversight Committee. However, the source and date of the data obtained must be acknowledged in text and/or graphic presentations (e.g., "Based on OPTN data as of January 1, 2000"). A copy of each published abstract, manuscript, or news release should be submitted to OPTN contractor and/or the Policy Oversight Committee for informational purposes as soon as practicable. Publications that use data collected for the OPTN shall include the following notice: *The data reported here have been supplied by [XXX], the OPTN contractor. The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the OPTN, or the U.S. Government.*

**10.5 COMMITTEE ACCESS TO DATA.** Confidential Information, as herein defined, shall not be made available in a public meeting. In a non-public forum or meeting setting, access to Confidential Information will be limited to members of the Board of Directors, members of permanent standing or ad hoc committees, OPTN contractor staff and individuals engaged as an adjunct to contractor staff. Access will be limited to the above described individuals, provided that these individuals are performing functions on behalf of the OPTN and are either bound by a fiduciary responsibility to the OPTN or a contractual obligation to the OPTN contractor to maintain the confidentiality of such data and information. These individuals shall have no ownership right in or to any of the Confidential Information and maintenance of the Confidential Information shall be a private and confidential matter which is required for the continued success of the OPTN and its business. This Confidential Information includes but is not limited to financial data and information; data and information relating to procedural and substantive needs, problems, developments and projects; and data and information regarding organ donors and recipients and institutions and medical personnel involved in organ transplantation, which constitute sensitive medical data or information subject to federal or state confidentiality statutes and regulations, all of which constitute trade secrets or confidential information of the OPTN. All such data and information together with business practices and procedures of the OPTN will be referred to collectively as "Confidential Information."

At such time as it becomes necessary to present or review candidate- and recipient- specific or center specific data or other Confidential Information, such data or Confidential Information will be provided in individual packets for review at that non-public meeting only. At the conclusion of the meeting all individual packets will be collected by the administrative staff, and no such data or Confidential Information will be permitted outside the meeting room except that maintained by administrative staff and adjunct personnel. When practicable, the Confidential Information will be displayed electronically via overhead projection or slide projection for discussion purposes thereby eliminating the need for individualized sets of the Confidential Information. Only OPTN

contractor staff, or government staff pursuant to contractual requirements, will be able to retain the data or Confidential Information in written or electronic form.

In no event shall any person, other than OPTN contractor staff and adjunct personnel in attendance in any non-public meeting be permitted to have access to these data or Confidential Information outside the meeting room. Cooperation and compliance with these procedures will ensure the integrity of the OPTN and foster the trust of those who are associated with or who have dealings with the OPTN.